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510(k) SUMMARY

WaisMed's B.I.G.™ - Bone Injection Gun

DEC 22 2006

Submitter's Name: WaisMed, Ltd.
Address: 91 Medinat Hayehudim Street
Herzliya
ISRAEL
Telephone Number: 972-9-9550213
Facsimile: 972-9-9516511

Contact Person: Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 13th Street, N.W.
Washington, D.C. 20004-1109
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Date prepared: September 29, 2006

Name of Device and Name/Address of Sponsor

B.I.G.™ - Bone Injection Gun
WaisMed, Ltd.
91 Medinat Hayehudim Street
Herzliya
ISRAEL

Common or Usual Name

Intraosseous infusion device

Classification Name

Hypodermic single lumen needle

Predicate Devices

WaisMed, Ltd., B.I.G. - Bone Injection Gun (K981853)
Vidacare Corporation, Humeral Head EZ-IO (K052408)

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Intended Use / Indications for Use

The B.I.G. - Bone Injection Gun is indicated for use in providing intraosseous access as an alternative to IV access during emergencies. Humeral head IO access is indicated when rapid fluid or pharmacological resuscitation is required and intravenous access is not possible. The device is for use in adult patients only.

Technological Characteristics

The B.I.G. - Bone Injection Gun consists of a trocar needle held by a piston. The piston is surrounded by a compressed spring. All components are contained in the device's housing. When the device is operated, the compressed spring is released and propels the trocar needle into the bone marrow.

Performance Data

The device was tested for both performance and safety. In all instances, the B.I.G. - Bone Injection Gun functioned as intended.

Substantial Equivalence

The B.I.G. - Bone Injection Gun is as safe and effective as the B.I.G. - Bone Injection Gun for use in the tibia and the Humeral Head EZ-IO. The B.I.G. - Bone Injection Gun has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indication for use and/or technological characteristics raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

WaisMed, Limited
C/O Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan & Hartson L.L. P.
555 Thirteenth Street, NW
Washington, DC 20004

DEC 2 2 2006

Re: K062940
Trade/Device Name: B.I.G. - Bone Injection Gun
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 28, 2006
Received: September 28, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

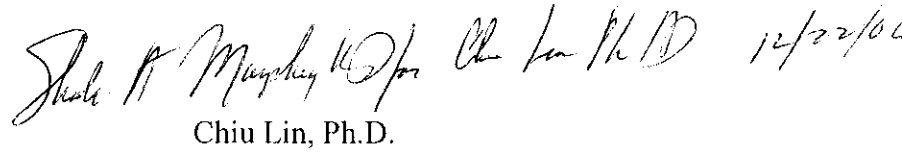
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known):_____

Device Name: B.I.G. - Bone Injection Gun

Indications for Use:

The Bone Injection Gun (BIG) is intended to provide intraosseous access as an alternative to IV access during emergencies. Humeral head IO access is indicated when rapid fluid or pharmacological resuscitation is required and intravenous access is not possible. The device is for use in adult patients only.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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